

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

March 30, 2020

Laura E. Radevski Technical & Regulatory Compliance Manager Chase Products Co. P.O. BOX 70 – Maywood, IL 60153

Subject: Label Amendment: Emerging Viral Pathogens Claim

Product Name: Champion Sprayon Spray Disinfectant Formula 3

EPA Registration Number: 498-179 Application Date: May 20, 2020

Decision Number: 560408

Dear Ms. Radevski:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Because you have opted to add statements pertaining to emerging viral pathogens to your label as described in the August 19, 2016, Guidance to Registrants: Process For Making Claims Against Emerging Viral Pathogens Not On EPA-Registered Disinfectant Labels ("Guidance"), https://www.epa.gov/sites/production/files/2016-

09/documents/emerging_viral_pathogen_program_guidance_final_8_19_16_001_0.pdf, you are subject to the following additional terms of registration:

- 1. You may make statements pertaining to emerging viral pathogens only through the following communications outlets: technical literature distributed exclusively to health care facilities, physicians, nurses and public health officials, "1-800" consumer information services, social media sites and company websites (non-label related). These statements shall not appear on marketed (final print) product labels.
- 2. Your statements pertaining to emerging viral pathogens must adhere to the format approved on the Agency-accepted master label.

- 3. You may make statements pertaining to emerging viral pathogens only upon a disease outbreak that meets all the following criteria:
 - a. The causative organism must be a virus that causes an infectious disease that has appeared in a human or animal population in the U.S. for the first time, or that may have existed previously but is rapidly increasing in incidence or geographic range.
 - i. For human disease, the outbreak is listed in one of the following Centers for Disease Control (CDC) publications:
 - A. CDC Current Outbreak List for "U.S. Based Outbreaks" (www.cdc.gov/outbreaks),
 - B. CDC Current Outbreak List for "Outbreaks Affecting International Travelers" with an "Alert" or "Advisory" classification (www.cdc.gov/outbreaks) (also released through the CDC's Health Alert Network (HAN) notification process)
 - C. Healthcare-Associated Infections (HAIs) Outbreaks and Patient Notifications page (www.cdc.gov/hai/outbreaks)
 - ii. For animal disease, the outbreak is identified as an infectious disease outbreak in animals within the U.S. on the World Organization for Animal Health (OIE) Weekly Disease Information page (www.oie.int/wahis 2/public/wahid.php/Diseaseinformation/WI).
 - A. The CDC or OIE has identified the taxonomy, including the viral family and/or species, of the pathogen and provides notice to the public of the identity of the emerging virus that is responsible for an infectious disease outbreak. Based on the taxonomy of the outbreak pathogen identified by the CDC or OEI, the pathogen's viral subgroup is enveloped.
 - B. The virus can be transmitted via environmental surfaces (non-vector transmission), and environmental surface disinfection has been recommended by the CDC, OIE or EPA to control the spread of the pathogen.
- 4. You may begin communicating statements pertaining to emerging viral pathogens only upon CDC or OIE's publication per term 3.a. of an outbreak of an emerging viral pathogen meeting all of the criteria of term 3. You must cease and remove all such non-label communications intended for consumers no later than 24 months after the original publication of the outbreak per term 3.a., unless the Agency issue written guidance to the contrary due to continued public health concerns. The emerging pathogen claim language may remain on the master label.
- 5. Terms from points 1 through 4 above shall become immediately void and ineffective if registration for use against Rhinovirus Type 39, ATCC VR-340, Strain 209 is suspended or cancelled or no longer meets the criteria for a disinfectant claim (see EPA Product

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Performance Test Guideline 810.2200). In addition, terms B.1 through B.4 above shall become immediately void and ineffective upon your receipt of evidence of ineffectiveness against any pathogen in a less-resistant Spaulding category.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, you may contact the disinfectants list at disinfectantslist@epa.gov.

Sincerely,

John Hebert, Chief

Regulatory Management Branch 1 Antimicrobials Division (7510P) Office of Pesticide Programs

Alu Must

Enclosure: stamped label

FRONT PANEL

ACCEPTED

03/30/2020

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 400, 470

498-179

KILLS COLD & FLU VIRUSES*

CAN BE USED ON SOFT SURFACES***

CHAMPION SPRAYON

SPRAY DISINFECTANT FORMULA 3

Kills 99.9% of germs (sanitizing)in 20 seconds**
Kills 99.9% of germs** (alternate language)

- KILLS MOST GERMS
- ELIMINATES ODORS
- PREVENTS MOLD AND MILDEW

KILLS FLU VIRUS*
KILLS PANDEMIC 2009 (H1N1) INFLUENZA A VIRUS*
KILLS RHINOVIRUS TYPE 39*

KILLS HIV-1 (AIDS VIRUS) ON PRECLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD AND BODY FLUIDS.

KILLS STAPHYLOCOCCUS AUREUS, SALMONELLA ENTERICA, PSEUDOMONAS AERUGINOSA, STREPTOCOCCUS PYOGENES, VANCOMYCIN-RESISTANT ENTEROCOCCUS FAECALIS (VRE), AND METHICILLIN-RESISTANT STAPHYLOCOCCUS AUREUS (MRSA).

NET WT X lb XX oz (XXX g)

KEEP OUT OF REACH OF CHILDREN CAUTION

See precautionary statements on back of can.

BACK PANEL

FORMULATED FOR HOSPITAL • SCHOOL • HOTEL • MOTEL • OFFICE • RESTAURANT • LOCKER AND REST ROOM • FACTORY • INSTITUTION • HOME • BEAUTY SHOP • BARBER SHOP [PET INDUSTRY]

SPRAY DISINFECTANT • SHAKE BEFORE USING

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

This product is not to be used as a terminal sterilant/high-level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high-level disinfection.

Kills HIV-1 (AIDS VIRUS) on precleaned environmental surfaces/objects previously soiled with blood and body fluids in health care settings or other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood or body fluids and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of HIV.

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV OF SURFACES/OBJECTS SOILED WITH BLOOD AND BODY FLUIDS.

PERSONAL PROTECTION: When handling items soiled with blood or body fluids use appropriate barrier protection such as disposable latex gloves, gowns, masks and eye coverings.

CLEANING PROCEDURE: Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of this disinfectant.

DISPOSAL OF INFECTIOUS MATERIALS: Blood and other body fluids must be autoclaved and disposed of according to Federal, state and local regulations for infectious waste disposal.

CONTACT TIME: Leave surface wet for 10 minutes.

After surface is cleaned, HOLD CAN UPRIGHT and spray 6 to 8 inches from surface to be treated until surface becomes wet. Allow spray to dry without wiping, or allow spray to contact treated surface for a minimum of 10 minutes prior to wiping.

FOR DISINFECTION OF INANIMATE SURFACES

This disinfectant spray is a germicide that kills Staphylococcus aureus, Salmonella enterica, Pseudomonas aeruginosa, Streptococcus pyogenes, Vancomycin-resistant Enterococcus faecalis (VRE) and Methicillin-resistant Staphylococcus aureus (MRSA). Use to disinfect metal or glazed porcelain urinals, plastic or

ceramic tile shower stalls, metal or plastic diaper pails, garbage cans, light switches and telephones, and non-wood surfaces of toilet seats, empty hampers, athletic equipment and lockers.

*Virucidal: Kills Rhinovirus Type 39 (the leading cause of the common cold). Kills Pandemic 2009 (H1N1) Influenza A Virus and it is also effective against flu virus on hard, nonporous inanimate surfaces.

DIRECTIONS: Clean object to be sprayed using usual cleaning methods. HOLD DISPENSER UPRIGHT and spray 6 inches from surface until surface is wet. Allow disinfectant spray to remain on the surface for 10 minutes before wiping off.

It kills Trichophyton mentagrophytes (athlete's foot fungus) on hard, nonporous inanimate surfaces in appropriate areas such as shower room floors, locker room benches or bath mats.

[EMERGING PATHOGEN CLAIM LANGUAGE

This product qualifies for emerging viral pathogen claims per the EPA's "Guidance to Registrants: Process for Making Claims Against Emerging Viral Pathogens not on EPA-Registered Disinfectant Labels" when used in accordance with the appropriate use directions indicated below

This product meets the criteria to make claims against certain emerging viral pathogens from the following viral category:

Enveloped Viruses For an emerging viral pathogen that is an	follow the directions for use for the following organisms on the label:
Enveloped virus	Rhinovirus Type 39, (ATCC VR-340), Strain 209

Champion SprayOn Spray Disinfectant Formula 3 has demonstrated effectiveness against viruses similar to [name of emerging virus] on hard, non-porous surfaces. Therefore, Champion SprayOn Spray Disinfectant Formula 3 can be used against [name of emerging virus] when used in accordance with the directions for use against Rhinovirus Type 39 on hard, non-porous surfaces. Refer to the CDC website at www.cdc.gov/outbreaks for additional information.

Or

[Name of illness/outbreak] is caused by [name of emerging virus]. Champion SprayOn Spray Disinfectant Formula 3 kills similar viruses and therefore can be used against [name of emerging virus] when used in accordance with directions for use against Rhinovirus Type 39 on hard, non-porous surfaces. Refer to CDC website at www.cdc.gov/outbreaks for additional information.

FOR SANITIZING INANIMATE, NON-FOOD CONTACT SURFACES

**Sanitizes: Kills 99.9% Staphylococcus aureus (staph), Klebsiella pneumoniae (K. pneumoniae), Escherichia coli, Campylobacter jejuni and Salmonella enterica on hard, nonporous surfaces in 20 seconds.

Use to sanitize inanimate, hard, non-porous, non-food contact surfaces

DIRECTIONS: Clean object to be sprayed using usual cleaning methods. HOLD DISPENSER UPRIGHT and spray 6 inches from surface until surface is wet. Allow disinfectant spray to remain on the surface for 20 seconds before wiping off.

FOR SANITIZING SOFT, NON-FOOD CONTACT SURFACES (FABRICS)

*** Sanitizes: Kills 99.9% Enterobacter aerogenes and Staphylococcus aureus on soft, non-food contact surfaces in 60 seconds.

Use to sanitize soft surfaces like couches, sofas, mattresses, pet beds, etc.

DIRECTIONS: Spray until fabric is wet. DO NOT SATURATE. Fabric must remain wet for 60 seconds. Let air dry. For difficult odors repeat application. Do not apply on silk, rayon acetate or satin fabrics. Always test on a hidden area of fabric first.

FOR CONTROL OF MOLD & MILDEW

Prevent mold and mildew on hard surfaces such as glazed ceramic, metal and glass, in basement closets, attic storage areas, summer cottages.

DIRECTIONS: Clean object by usual cleaning methods. HOLD DISPENSER UPRIGHT and spray 6 inches from surface until surface is wet. Repeat application every seven days or when new growth appears.

FOR SPACE DEODORIZER & AIR FRESHENER

Use to deodorize meeting room, classroom, kitchen, bathroom, sickroom, living room and churches.

DIRECTIONS: HOLD CAN UPRIGHT and point valve opening away from face. Spray upward for 3 seconds into corners as well as center of room, filling room with mist.

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS & DOMESTIC ANIMALS

CAUTION

May cause eye irritation. Avoid contact with the eyes and skin. Avoid breathing of spray mist. Avoid contamination of foodstuff.

FIRST AID

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lens, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

PHYSICAL OR CHEMICAL HAZARDS

FLAMMABLE. Contents under pressure. DO NOT PUNCTURE. Do not use or store near heat or open flame. Exposure to temperatures above 120°F may cause bursting. Never throw container into fire or incinerator. Do not spray on varnished, painted or plastic surfaces.

STORAGE & DISPOSAL

STORAGE: Store in a cool, dry area away from heat or open flame.

DISPOSAL: Do not reuse empty container. This container may be recycled in one of the limited number of aerosol recycling centers in the country. Before recycling, empty the can by using the product according to the label. DO NOT PUNCTURE! If recycling is not available, wrap the container and discard in the trash.

THE USER OF THIS PRODUCT ASSUMES ALL RISKS OF USE, STORAGE AND HANDLING NOT IN ACCORDANCE WITH ITS DIRECTIONS AND CAUTIONS.

ACTIVE INGREDIENTS:

n-Alkyl (60% C14, 30% C16, 5% C12, 5% C18)	
dimethylbenzyl ammonium chloride	0.1%
n-Alkyl (68% C12, 32% C14)	
dimethyl ethylbenzyl ammonium chloride	0.1%
Ethanol	30.8%
OTHER INGREDIENTS:	69.0%
Total	100.0%

CONTAINS SODIUM NITRITE

EPA Reg. No. 498-179-XXXXX

EPA Est. No. 498-IL-1

KEEP OUT OF REACH OF CHILDREN

[OPTIONAL: Questions about this product? Call (708) 865-1000.

MEDICAL EMERGENCY INFORMATION ONLY:

ChemTel, Inc. (800) 255-3924]

OPTIONAL:

Contains no CFCs or other ozone depleting substances Federal regulations prohibit CFC propellants in aerosols

[OPTIONAL RECYCLE SYMBOL]

[OPTIONAL MADE IN USA GRAPHIC]

[OPTIONAL UPC SYMBOL]

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P.O. Box 70 - Maywood, IL 60153 www.chaseproducts.com

[OPTIONAL TEXT – EXAMPLE: BOXED ON BACK PANEL]

A. 10-min Disinfection against Bacteria on hard nonporous surfaces:

Staphylococcus aureus (ATTC 6538)

Salmonella enterica (ATTC 10708)

Pseudomonas aeruginosa (ATTC 15442)

Streptococcus pyogenes (ATCC 9342)

Vancomycin-resistant Enterococcus faecalis (VRE) (ATCC 51299)

Methicillin-resistant Staphylococcus aureus (MRSA) (ATCC 33591)

B. 10-min Disinfection against Virus on hard nonporous surfaces:

Human Immunodeficiency Virus Type 1

(HIV-1) (AIDS Virus) (HTLV-III_{RF} strain of HIV-1)

Swine Influenza A Virus (ATCC VR-333)** – Influenza A/Swine/Iowa/15/30 (H1N1)

Rhinovirus type 39 (ATCC VR-340)

C. 10-min Disinfection against Fungi on hard nonporous surfaces:

Trichophyton mentagrophytes (Athlete's Foot Fungus) (ATCC 9533)

D. 20-sec Sanitization against Bacteria on hard nonporous surfaces:

Staphylococcus aureus (ATCC 6538)

Klebsiella pneumoniae (ATCC 4352)

Escherichia coli (ATCC 11229)

Campylobacter jejuni (ATCC 33560)

Salmonella enterica (ATCC 10708)

E. 60-sec Sanitization against Bacteria on soft, non-food contact surfaces.

Enterobacter aerogenes (ATCC 13048)

Staphylococcus aureus (ATCC 6538)

8-XXXX		
BOTTOM OF LABEL		